

APR 27 2004

Feb. 12th, 2004

Traditional 510(k) Summary

Image-Arena Applications Research-Arena Applications

Image-Arena Platform 3.x
Research-Arena Platform 1.x
4D Cardio-View 2.x
4D LV-Analysis 2.x
4D Surgical-View 2.x
4D Echo-View 6.x
4D Easy-View 3.x
4D Omni-View 3.x
4D Parametric-View 1.x
Echo-Com 3.x
Image-Com 3.x
Doku-Com 3.x
Axius Quantitative Strain Rate Imaging (Axius QSI)
Axius M-Mode DTI (Axius M-Mode DTI)
Axius Advanced Contrast Quantification (Axius ACQ)
Axius Edge Assisted Ejection Fraction (Axius Edge Assisted EF)

Name and Address

TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person

Ralf Janitz
QM & RA Manager
Phone ++49-89-32175-830
Fax ++49-89-32175-750

Common, Classification & Proprietary Names

Common Name: Various Ultrasound Image Analysis
Software & System

Classification Name: Ultrasonic Pulsed Echo Imaging System





Proprietary Name(s):

Image-Arena Applications Research-Arena Applications

Image-Arena Platform 3.x
Research-Arena Platform 1.x
4D Cardio-View 2.x
4D LV-Analysis 2.x
4D Surgical-View 2.x
4D Echo-View 6.x
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Axius Edge Assisted Ejection Fraction (Axius Edge Assisted EF)

Predicate Device

TomTec	Echo-View	K022824
TomTec	Echo-Com	K001592
Siemens	Sequoia™ Diagnostic Ultrasound System Signature II, Axius™ SW Applications	K022567
Siemens	Sequoia™ Diagnostic Ultrasound System Axius™ SW Applications	K032114

Device Description

The hardware requirements are based on an Intel Pentium high performance computer system and Microsoft® Windows XP Professional™ or Microsoft® Windows 2000 Professional™ Operating System standards.

The Image-Arena/Research-Arena Applications are a software tool package designed for analysis, documentation and archiving of ultrasound studies in multiple dimensions. The Image-Arena/Research-Arena Applications software tools are modular structured and consist of different software modules, combining the advantages of the previously FDA 510(k) cleared TomTec software product lines Echo-View and Echo-Com and Siemens Axius™ software applications. The



different modules can be combined on the demand of the users to fulfil the requirements of a clinical researcher or routine oriented physician.

The Image-Arena/Research-Arena Applications offer features to import different digital 2D, 3D and 4D (dynamic 3D) image formats based on defined file format standards (DICOM-, HPSONOS-, TomTec- file formats) as well as analogue video acquisition in one system, thus making image analysis independent of the ultrasound-device or other imaging devices used.

Offline measurements, documentation in standard report forms, the possibility to implement user-defined report templates and instant access to the stored data through digital archiving make it a flexible tool for image analysis and storage of different imaging modalities data including B-mode, M-mode, Pulsed (PW) Doppler mode, Continuous (CW) wave Doppler mode, Power Amplitude Doppler mode, Color Doppler mode, Doppler Tissue Imaging and 3D/4D imaging modes.

Intended Use

The Image-Arena/Research-Arena Applications software tool package is intended to acquire, store, retrieve, analyze and report digital ultrasound studies. The Image-Arena Platform and the Research-Arena Platform are based on a SQL – database intended as image management system especially for medical ultrasound studies.

The Image-Arena/Research-Arena Applications software can import certain digital 2D or 3D image file formats for 2D/3D and 4D tomographic reconstructions and surface rendering.

The software is suited to stand-alone workstations as well as networked multi-system installations and is therefore an image management system for research and routine use in both physician practices and hospitals. It is intended as a general purpose digital medical image processing tool for cardiology, radiology, neurology, gastroenterology, urology, surgery, obstetrics and gynecology.

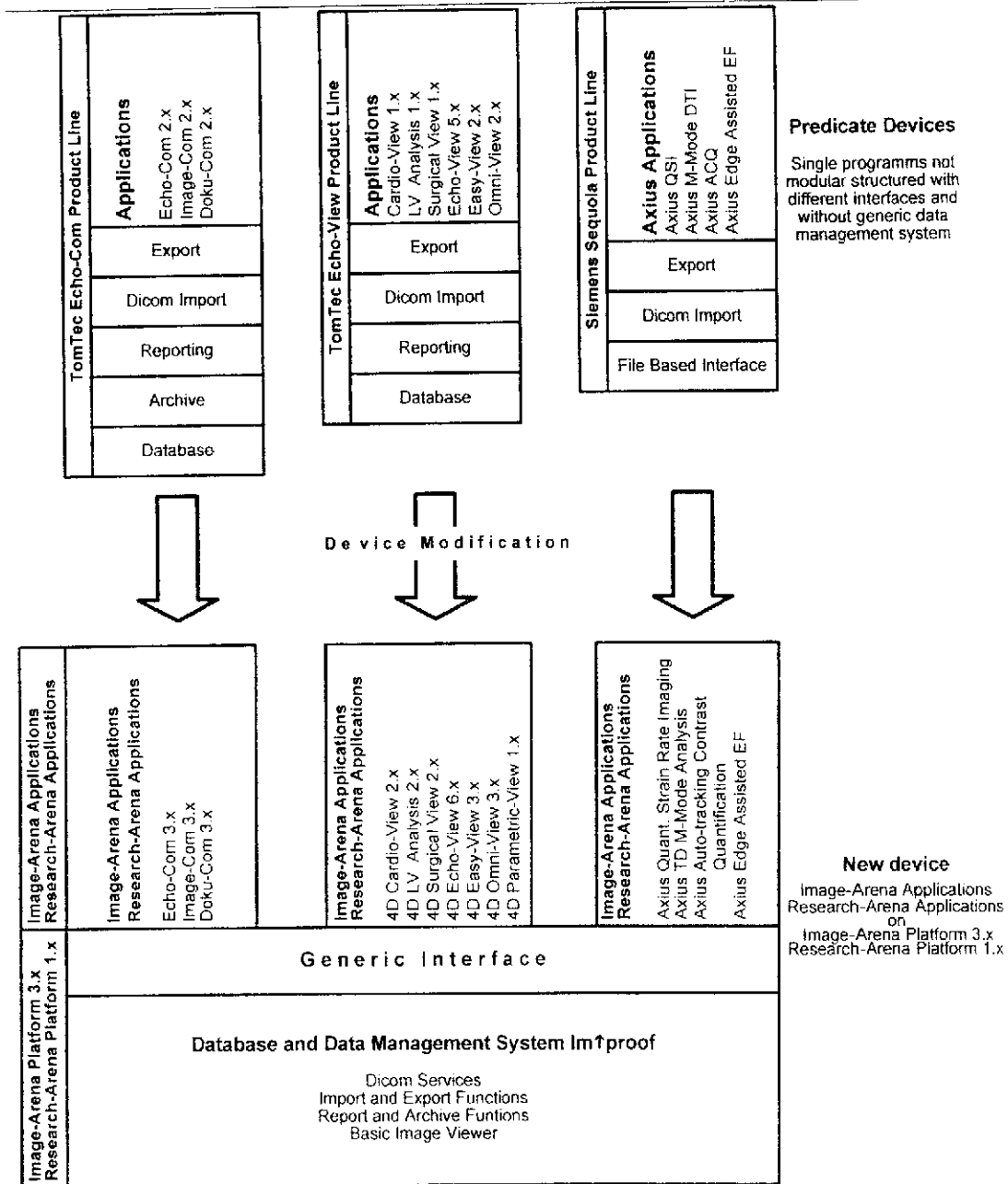
Technological Characteristics Comparison

The Image-Arena/Research-Arena Applications software tool package is modular structured and consists of different software modules, combining the advantages of the previously FDA cleared software products:

TomTec Echo-View, K022824

TomTec Echo-Com, K001592

Siemens Sequoia™ Diagnostic Ultrasound System Signature II, Axisus™ SW Applications K022567 and K032114.



From single programs to a modular structured tool package



The Image-Arena/Research-Arena Applications software is the combined modified modular structured version and follow-up product and has been transferred to Microsoft® Windows XP Professional™ operating system standards. The graphic user interface has been improved for faster and easier application.

The Image-Arena Platform/Research-Arena Platform based on SQL – database has a generic interface that enables the professional practitioners to combine the Image-Arena/Research-Arena Applications software very easy and generate image management systems especially for medical ultrasound studies.

Test Discussion

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release.

Test Conclusions

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally conforms to the system performance specifications.

Munich, Feb. 12th 2004


Ralf Janitz
QM & RA Manager



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2004

Mr. Ralf Janitz
Manager, Regulatory Affairs
TomTec Imaging Systems
Edisonstr.6, D-85716
Unterschleissheim
GERMANY

Re: K040546
Trade/Device Name: Image-Arena Applications,
Research-Arena Applications
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo
imaging system
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler
imaging system
Regulatory Class: II
Product Code: 90 LLZ, IYN, and IYO
Dated: February 27, 2004
Received: March 9, 2004

Dear Mr. Janitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

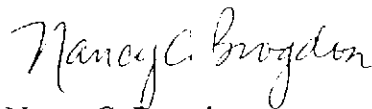
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for use

510(k) Number (if known): **K040546**

Device Name: **Image-Arena Applications, Research-Arena Applications**

Indications For Use:

Intended Use Summary for Image-Arena/Research-Arena Applications

The Image-Arena/Research-Arena Applications software tool package is intended to acquire, store, retrieve, analyze and report digital ultrasound studies. The Image-Arena Platform and the Research-Arena Platform are based on a SQL – database intended as image management system especially for medical ultrasound studies.

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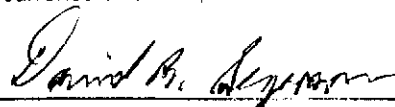
Prescription Use ☒
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040546

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